REMARKS

Summary of Changes Made

The Application was filed with 14 claims, and claims numbering up to 27 were later added. Claims 2, 3, 7-9, 11-14, 21, and 22 had been canceled previously. Presently claims 28-31 are added, and claim 24 is canceled. Accordingly, claims 1, 4-6, 10, 15-20, and 23, and 25-31 and (19 claims) are pending in the application. If the new claims cannot be entered into the record, then it is respectfully requested that, at least the argumentation below be added. No new matter has been added.

Claim Rejections – 35 U.S.C. 112, first paragraph

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner believes that the limitations of claim 24 do not find support in the specification as filed. The Examiner believes that a non-cross linked article is not supported in the specification.

The Examiner will note that claim 24 is canceled thus rendering moot the rejection.

Claim Rejections – 35 U.S.C. 103(a) - (Zecchino/Kojima)

Claims 1, 4-6, 10 and 15-20 and 23 are rejected as obvious in view of U.S. Pat. No. 6497887 to Zecchino et al., ("Zecchino") in view of U.S. Pat. App. Pub. No 2002/0068683 to Kojima, ("Kojima").

Applicants disagree with Examiner's opinion that the volumetric limitations according to step (a) of claim 1 and the geometrical sphere shape according to claim 6 are obvious from Zecchino in view of Kojima.

Zecchino explicitly refers to membranes (abstract; column 4 line 53 ff.) or to dry films or blocks which are sliced or cut into application pieces with a thickness of 0.1 to 1.5 mm thickness (column 3 lines 47 to 52).

Accordingly, Zecchino neither refers to sphere-shaped articles nor to a shaped article with a diameter of 3 to 60 mm. Furthermore Zecchino does not refer to shaped articles containing skeleton-forming agents, proteins being excepted.

The present invention provides a method for using improved shaped articles, which are intended for external use, especially for application onto the skin or hair. According to page 4, lines 5 to 18 of the specification, the improvement in the shaped articles can be seen in:

a) the regular sphere-form, providing pleasant appearance, improved packaging and transporting capacity, standardized and uniform active ingredient amounts as well as uniform and homogeneous dissolution kinetics
b) large-format of 3 – 60 mm in diameter, allowing single-use application per article,
c) improved dissolution, which includes uniform and standardized dissolution behaviour as well as a high dissolution rate of less than 4 minutes.

Zecchino:

a) Zecchino refers to shaped articles in the form of films or blocks which are sliced into the application form of membranes. Accordingly, Zecchino refers to sheet-like application forms only.

b) The membranes according to Zecchino, which are intended for external application, exhibit a thickness of 0.1 – 1.5 mm, which are then applied onto the skin per sheet-like membrane in a single-use application in dry or pre-moistened state. Complete dissolution of the sheet-like membrane is carried out onto the skin by rubbing the dissolved material into the skin (column 4, line 62 to column 5, line 7). This clearly indicates, that the membranes according to Zecchino do not exhibit ready and fast dissolution kinetics and thus do not form a solution or a gel upon contacting the shaped article with an aqueous solution according to claim 1 step (b) followed by application to the skin of the solution according to step (c) of the present invention.

c) The membranes according to Zecchino mandatorily comprise partially cross-linked polymers as pointed out earlier. A person skilled in the art is well aware, that partial cross-linking mandatorily limits the dissolution rate. As a result, according to Zecchino only thin films of approximately 0.1 to a maximum of 1.5 mm thickness are suitable for dissolution and application for external application. As pointed out above,

the sheet-like membranes according to Zecchino are explicitly intended to be applied to the skin in the form of stable sheet-like membranes before being completely dissolved and rubbed into the skin. Accordingly, due to their two-dimensional sheet-like appearance, such films are limited in the external application to extended, preferably plain skin areas. Instead, a regularly shaped article in the form of a sphere can be dissolved and applied more comfortable with more variety with respect to the region of application on the e.g. human body. Furthermore, a shaped article in the form of a sphere is more pleasant in its appearance and packaging and transporting is easier.

A sphere exhibits much more ambitious dissolution kinetics than a thin flat film, as the distance to the inner core is much greater in a sphere with a diameter of 3 – 60 mm than in a film of only 1.5 mm. This plays an important role for uniform, homogeneous and fast dissolution of the shaped articles for external application. Zecchino only refers to dissolvable / dissolved articles with a maximal thickness of 1.5 mm (resulting in a distance to the inner core of maximal 0.75 mm). In contrast, the improved sphere-shaped articles of the present invention exhibit a minimum diameter of 3 mm (resulting in a minimum distance to the inner core of 1.5 mm). Additionally, the membranes according to Zecchino remain stable and sufficiently undissolved, even upon contact with liquids, to be applied in the form of pre-moistened membranes although they exhibit maximally half the distance to the inner core compared to the articles according to the present invention. This shows that the membranes according to Zecchino not only differ in their volumetric and geometric appearance but even more in their dissolution behaviour, which results from their differing chemical compositions.

The claimed method differs from Zecchino not only in the volumetric and geometric dimensions but also in the specific dissolution behavior and the mode of application of the readily and homogeneously dissolved article, which is then applied in the form of a solution or gel instead of a pre-moistened still form-stable article. Such difference is realized by using the improved articles according to the present invention, which exhibit the specific combination of uniform and fast solubility with large-format (comprising a minimum distance to the inner core of the article of 1.5 mm or more).

In new claims 28-31, the improvement in the shaped articles is supported by the selection of the specific geometrical form, especially a sphere, and the specific selection of a low-viscosity skeleton-forming agent with a viscosity of less than 2000 mPa • s of a 1 per-cent-by-weight solution or suspension thereof in water at 20°C and at pH 6-8 (see specification page 7 lines 5 to 27 and page 17, lines 23 to 32).

Furthermore, the sphere shaped articles according to the present invention preferably comprises at least 10 wt.% of such selected skeleton-forming agent (see specification page 14 line 27 to page 15 line 2) which supports the mechanical strength and cohesion of such large-format sphere-shaped articles.

The improved dissolution behaviour is further supported by the specific density of the sphere-shaped articles of the present invention (see specification page 19 line 32 to page 20 line 5) and corresponds to the quantity of skeleton-forming agent (see specification page 19 lines 10 to 21).

Kojima:

Kojima only refers to solid shaped articles, e.g. sphere shaped articles, in the form of solid blocks which explicitly do not rehydrate throughout the whole material upon contact with water, as explained in detail in Amendment H, filed 20 January 2010. Accordingly Kojima, also fails to disclose easily-soluble large-format articles.

As even the thin membranes according to Zecchino alone are obviously not at all intended for fast and ready dissolution, due to the intended application scheme in dry or stable pre-moistened form, an article just varied with respect to the volumetric and geometric dimensions in view of Kojima would neither be suitable for the claimed use.

Accordingly, even if a skilled person would vary the dimensions of an article according to Zecchino this would not result in the articles and claimed use according to the present invention.

Applicants further maintain their disagreement with the examiners opinion that example 2 of Zecchino discloses a freeze-dried membrane which is free of ingredients which are consistent with the definition of "protein-based skeleton forming agents". In this context Applicants attempt to clarify the situation with the following comment: The present invention excludes protein-based skeleton-forming agents, wherein skeleton-forming agents refer to hydrocolloids – that is to say (partially) water soluble natural or synthetic polymers (see specification page 6, paragraph 3).

Also for reasons of clarification it is pointed out (page 8, paragraph 2) that protein-based active substances such as e.g. enzymes or hormones, which are well known to be neither polymers nor hydrocolloids, may be present in the articles of the invention. It then becomes apparent for the skilled artisan that protein-based active substances of the invention will not comprise skeleton-forming protein-based compounds - that is to say polymeric protein-based substances such as e.g. collagen.

According to Zecchino (column 3, lines 15 to 33), the 1 % soluble collagen used in Example 2 may function as a film-forming agent. It is apparent for a skilled person, that film-forming properties are related to skeleton-forming properties. Besides, as long as a proteinaceous compound (soluble collagen) exhibits skeleton-forming activity, which has been shown by the cited prior art, such compound is in any case excluded from the present invention, regardless of the concrete use intended by Zecchino. Accordingly, as the soluble collagen of example 2 falls under the definition of substances explicitly excluded from the claimed invention, example 2 does not disclose the composition of an article according to the instant invention.

In this context we emphasize that we do not agree with the examiners estimation that the cited documents U.S. 5,387,415, U.S. 5,384,129 U.S. 5,401,502 and U.S. 5,405,616, which all refer to the cross-linking properties of collagen, are not persuasive due to collagen amounts exceeding 50 % w/w. Actually, the cited documents substantiate that collagen is well known to exhibit cross-linking activity and thus per se acts as a skeleton-forming agent. Accordingly, the cited documents together with Hawley's Condensed Chemical Dictionary, which was cited by the examiner, clearly substantiate that soluble collagen according to example 2 of Zecchino belongs to the group of protein-based skeleton-forming agents, which are excluded from the present invention regardless of their concrete amount or any heat treatment process. As example

2 comprises protein-based skeleton-forming agents in the form of collagen it must be different from the shaped articles according to the present invention regardless of its concrete amount or possible cross-linking capacity. And thus it would not be sufficient to merely vary the volumetric and geometric dimensions, e.g. in view of Kojima, to result in the present invention.

This reasoning is further supported by the above discussion of the obvious differences in the dissolution behavior between the articles of the present invention and the membranes according to Zecchino. Additionally, Applicants maintain their further arguments hereto presented in Amendment "J," filed 29 April 2010.

In fact, to provide an improved shaped article as it is subject of the present invention, comprising such a specific combination of selected technical features, for the new claimed use according to claim 1, a person skilled in the art would have to carry out far more than routine variation and thus the present invention can not be considered as being prima facie obvious from Zecchino, neither alone nor in view of Kojima.

Conclusion

In light of the foregoing, it is respectfully submitted that the present application, including claims 1, 4-6, 10, 15-20, and 23-31, is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to Deposit Account No. 18-0160, Order No. GIL-16027.

Respectfully submitted,
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